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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products
Liability Litigation

No. MD-15-02641-PHX-DGC

**PLAINTIFFS' MOTION TO
EXCLUDE DEFENSE EXPERT
OPINIONS UNDER FED. R. EVID.
702 BASED ON THEIR USE OF
THE CRIMINAL LAW
STANDARD OF CERTAINTY**

Pursuant to Federal Rule of Evidence 702, Plaintiffs move this Court for an order excluding Defense Expert Opinions under Fed. R. Evid. 702 based on their use of the criminal law standard of certainty. Plaintiffs' motion is supported by the Memorandum of Law set out below and exhibits attached thereto.

MEMORANDUM OF LAW

I. INTRODUCTION

In the United States, the burden of proof for plaintiffs in civil cases is by a preponderance of evidence. The preponderance standard applies to each element of the claim, including causation. But two of Bard's experts, Drs. Clement Grassi and Christopher Morris, used a far higher standard of proof to form their opinions, including those concerning core issues in this case, such as whether Bard's filters fracture at unacceptably high rates or present unreasonably high rates of complication, and whether the risk increases the longer the filters remain implanted. Drs. Grassi and Morris opine

1 that the evidence on which Plaintiffs’ experts base their opinions does not allow for “more
 2 than 90%” certainty or “certainty beyond any reasonable doubt.” Pursuant to Rule 702
 3 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), Plaintiffs
 4 therefore move to exclude the testimony of Drs. Grassi and Morris because the beyond-a-
 5 reasonable-doubt standard is (1) irrelevant; and (2) will confuse and mislead the jury to
 6 believe that Plaintiffs cannot meet their burden of proof. Any attempt by Bard, through
 7 these experts, to suggest that Plaintiffs must prove that Bard’s filters fail at unacceptably
 8 rates “beyond any reasonable doubt” or with “more than 90% certain[ty]” will prejudice
 9 Plaintiffs, holding their experts and them to an erroneously high burden of proof.

10 Use of the wrong standard of proof violates the letter and spirit of Fed. R. Evid.
 11 702, 703, and *Daubert*, which mandate that expert testimony must be reliable, relevant
 12 and must “assist the trier of fact.” Opinion testimony based on an improper standard will
 13 not “assist” the jury, rather it will confuse them. And, opinions based on an incorrect
 14 standard fail to pass the “relevance” prong of *Daubert*.

15 Like a scrambled egg that cannot be unscrambled, there is no way to correct this
 16 problem at trial other than by preclusion, because the experts used the wrong standard *to*
 17 *form* their opinions. The jury will be presented with an apples vs. oranges dilemma;
 18 presented with differing opinions from Plaintiffs’ experts and Drs. Grassi and Morris, the
 19 jurors will have no way to reconcile these differing opinions, because they were formed
 20 based on the experts’ application of very different standards.

21 In addition, Dr. Morris’s statement about whether filter fracture causes symptoms,
 22 and Dr. Grassi’s statements about his personal experience with filters, should be excluded.
 23 As explained below, these opinions are speculative and anecdotal; they are not based on
 24 consideration of reliable data.

25 **II. FACTUAL BACKGROUND**

26 Bard has disclosed Drs. Clement Grassi and Christopher Morris – both
 27 interventional radiologists – as two of their ten MDL expert witnesses. Drs. Grassi and
 28 Morris offer opinions on the adequacy of the scientific studies IVC filter fracture rates.

1 Dr. Morris is an Interventional Radiologist and Professor of Radiology and Surgery
 2 at the University of Vermont. Exhibit 1 (Morris Report at 1).¹ In his report, Dr. Morris
 3 devoted several paragraphs to studies on filter fracture. When addressing articles
 4 regarding high fracture rates of Bard filters, he dismissed them for having “weak” design,
 5 low power, or both, and went into detail about his criticisms of the studies’ methods. *Id.*
 6 at 25-26. When addressing studies purporting to show low fracture rates for Bard filters,
 7 however, Dr. Morris limited himself to a terse summary of the results. Although he
 8 commented that “many of these studies are fraught with the same limitations as the studies
 9 that show high fracture rates in Bard [filters],” Dr. Morris did not identify any specific
 10 limitation or offer criticism of any of the low fracture rate studies. *Id.* at 26-27. In the
 11 section of his report addressing Bard filter “low” complication rates, he did not even
 12 mention that all of the studies with low fracture rate findings were short-term follow-up
 13 studies (a critical omission), or that that multiple studies find that fracture rates increase
 14 the longer a filter is implanted. Finally, he wrote that “most limb fractures remain
 15 asymptomatic.” *Id.* at 25.

16 At his deposition, Dr. Morris explained that the level of certainty that he used in
 17 reaching his opinions was “a high level of certainty.” Exhibit 2, Morris Dep. at 139-140.
 18 Dr. Morris testified that “a high level of certainty” means “more than 90% certainty.”
 19 Morris Dep. at 140:4; 143:13-24. Dr. Morris testified that “the literature does not support
 20 to a *high level of certainty* that the complication rate increases exponentially” with time.
 21 Morris Dep. at 172: 14-16. (emphasis added). Dr. Morris also testified that when
 22 assessing the medical literature, his question is, “how can I make 100 percent certain
 23 opinions based on literature which is less than Level I or Level II evidence?” *Id.* at 142.

24 Although Bard’s counsel elicited from Dr. Morris on re-direct examination a
 25 statement that “reasonable degree of medical certainty” meant 51%, *id.* at 344, he
 26

27 ¹ References to Dr. Morris’s and Dr. Grassi’s reports are only to his MDL report, not to
 28 the one he submitted in the medical monitoring class action. The motions apply to the
 opinions in the medical monitoring class action as well, to the extent they will be offered
 in that case.

1 contradicted this statement throughout his deposition testimony. As noted above,
2 Dr. Morris asserted that his opinions were based on “a high level of certainty,” which he
3 defined as “more than 90% certainty.” *Id.* at 140:4; 143:13-24. Dr. Morris based this
4 approach for evaluating evidence not on a published methodology, but on his admiration
5 for his brother:

6 My touchstone, is my brother, who I’m very close to, who’s a
7 top ten neuroscience researcher ... so I gauge that as being
8 100 percent certain. He has \$50 million in grants. He’s the
9 quintessential medical scientist that relies on Level I and Level
10 II evidence. So when I compare his body of work, which I
11 know -- which I’ve been following my entire life -- again, he’s
12 -- you know, he’s very close to me and -- and I really respect
13 his degree of scientific validity.

14 *Id.* at 141:24-142:14.

15 Dr. Morris then explained that he required a high level of proof to be convinced
16 that there were problems with Bard filters: “When I compare that to the literature that’s
17 available regarding IVC filters, there’s basically no -- no comparison, so how can I make
18 100 percent certain opinions based on literature which is less than Level I or Level II
19 evidence?” *Id.*

20 With respect to the rate of symptoms caused by limb fractures, Dr. Morris was
21 asked whether they could become life-threatening, *id.* at 209:7-10, to which he responded
22 “rarely.” He later admitted that this was speculation on his part:

23 Q: “[Y]ou cannot say to a reasonable degree of scientific
24 certainty that this event [patient death from Bard filter fracture]
25 is rare unless you know the answer to the question of whether
26 it’s recognized when it happens on a regular basis, right?

27 A. It’s speculation.

28 *Id.* at 212:24-213:6.

Dr. Grassi offered similar testimony. Like Dr. Morris, he is an interventional
radiologist. Dr. Grassi also provided a review of the medical literature, Exhibit 3 (Grassi
Report) at 4-11, and he offered three statements relevant to this motion:

1 (1) With respect to fractures, "... in my view, the higher rates of delayed filter
2 fracture for the Bard Recovery® and Bard G2® filters reported by
3 Nicholson, et al.. have not been validated and the study does not reliably
4 establish a fracture rate for Bard Recovery® and G2® vena cava filters."

5 (2) "To my knowledge, in the medical literature, there has been no study
6 proving that tilt, migration, and/or perforation increases the risk of
7 subsequent filter fracture."

8 (3) "In my own experience, I have not encountered unexpectedly high
9 complication rates with the Bard filter devices."

10 *Id.* at 9, 10, 12.

11 At his deposition, Dr. Grassi was asked the cause of fractures. He responded that
12 "there has not been a mechanism which has yet been proven." Exhibit 4 (Grassi Dep.) at
13 91:8-10. When asked to elaborate on what level of proof would be required, he said he
14 would look for a "convincing explanation." Specifically, "I would look for evidence
15 where I felt certain beyond any reasonable doubt." *Id.* at 94:10-11. (emphasis added).
16 He further testified that "overall" he applied this standard for his opinions in this case. *Id.*
17 at 94:10-15. When asked about whether longer in-dwell times increase the risk of
18 complications, Dr. Grassi invoked the same absolute-certainty standard, explaining, "So
19 my own opinion is that further work has to be done on this particular subject before I'm
20 *convinced* of that direct relationship." *Id.* at 128:8-13. (emphasis added).

21 With respect to his personal experience, Dr. Grassi did not testify that he ever
22 systematically evaluated his patients for filter complications. He implanted and retrieved
23 no Recovery filters, and he retrieved approximately six of each of the other filters at issue
24 (G2/G2x, Eclipse, Meridian, and Denali). *Id.* at 51-63. Of these limited number of
25 retrievals, he saw at least one perforation of a G2 (out of approximately four removed).
26 *Id.* at 56.

1 **III. LEGAL ARGUMENT**

2 Under *Daubert*, a trial court acts as a “gatekeeper” to the admission of expert
 3 scientific testimony under Rule 702. That is, the court must conduct a preliminary
 4 assessment to “ensure that any and all scientific testimony or evidence admitted is not
 5 only relevant, but reliable.” *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 589
 6 (1993). Reliable testimony must reflect “scientific knowledge,” which implies a
 7 grounding in scientific methods and procedures, not merely subjective belief or
 8 unsupported speculation. *Id.* at 590. The inferences or assertions drawn by the expert
 9 must be “derived by the scientific method.” *Id.* In essence, the court must determine
 10 whether the expert’s work product amounts to “good science.” *Daubert v. Merrell Dow*
 11 *Pharms., Inc.*, 43 F.3d 1311, 1315 (9th Cir.1995) (“*Daubert II*”) (quoting *Daubert*, 509
 12 U.S. at 593). The relevancy, or “fit,” prong requires that the testimony be “‘relevant to
 13 the task at hand,’ ... *i.e.*, that it logically advances a material aspect of the proposing
 14 party’s case.” *Id.* (quoting *Daubert*, 509 U.S. at 597).

15 These requirements are necessary because any expert’s opinion “can be both
 16 powerful and quite misleading because of the difficulty in evaluating it.” *Daubert*, 509
 17 U.S. at 595 (internal quotations and citations omitted). As the Ninth Circuit noted,
 18 “Maintaining *Daubert*’s standards is particularly important considering the aura of
 19 authority experts often exude, which can lead juries to give more weight to their
 20 testimony.” *Elsayed Mikhtar v. California State Univ., Hayward*, 299 F.3d 1053, 1063-64
 21 (9th Cir. 2002). Because of this risk, the court exercises more control over experts than
 22 over lay witnesses in weighing possible prejudice against the probative value of the
 23 testimony under Rule 403. *Daubert*, 509 U.S. at 595.

24 First, the above opinions of Dr. Morris and Dr. Grassi should be excluded because
 25 they are based on an incorrect standard of certainty. Second, the opinions of Dr. Morris
 26 and Grassi that are based on speculation or unreliable anecdotal experience should also be
 27 excluded because they are not based on reliable data.
 28

A. Opinions requiring proof beyond a reasonable doubt should be excluded.

The “preponderance of the evidence standard in a civil case applies to any element that must be proven, which includes elements developed by expert opinion, such as the rate of fractures of a filter. The higher standard employed by Dr. Morris and Dr. Grassi should be excluded because it is not relevant to the claims at issue and not helpful to the jury.

Although Drs. Morris and Grassi did not disclose in their reports that they use this improperly high standard of proof to determine if they were “convinced” of those and other propositions, they revealed this standard in their deposition testimony.

1. The Standard of Proof in a Civil Case is “More Likely than Not,” and it Applies to Expert Opinion under the *Daubert* Standard.

Longstanding legal principles govern the standard of proof in a civil case. In Arizona and elsewhere, Plaintiffs must prove the elements of the claims by a preponderance of evidence. This holds true for evidence of causation, including expert testimony. Expert opinion based on a different standard should not be admitted both because it is confusing (and certainly not helpful) to the trier of fact and because it is by definition, irrelevant.

“The legal standard, after all, is preponderance of the evidence, *i.e.*, more-probable-than-not, and that applies to causality as to any other element of a tort cause of action. Rule 702, a rule of threshold admissibility, should not be transformed into a rule for imposing a more exacting standard of causality than more-probable-than-not simply because scientific issues are involved.” *In re Ephedra Prod. Liab. Litig.*, 393 F. Supp. 2d 181, 190 (S.D.N.Y. 2005). “Plaintiffs... need only prove that causation is more-probable-than-not.” *Id.* at 193; *accord McClellan v. I-Flow Corp.*, 710 F. Supp. 2d 1092, 1138 (D. Or. 2010) (“plaintiffs’ ultimate burden is proof by a preponderance of the evidence.”).

The *Daubert* court rejected the position taken by Drs. Morris and Grassi that causation inferences must be based on conclusive evidence of absolute certainty. “It would be unreasonable to conclude that the subject of scientific testimony must be

1 ‘known’ to a certainty; arguably, there are no certainties in science.” *Daubert*, 509 U.S. at
2 590.

3 The Ninth Circuit agrees: “Lack of certainty is not, for a qualified expert, the same
4 thing as guesswork.” *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010). And there are
5 good reasons why it is unreasonable for medical experts to express causation opinions
6 under a “beyond a reasonable doubt” standard. “The human body is complex, etiology is
7 often uncertain, and ethical concerns often prevent double-blind studies calculated to
8 establish statistical proof.” *Id.* at 566. *See also Messick v. Novartis Pharm. Corp.*, 747
9 F.3d 1193, 1198 (9th Cir. 2014) (The Ninth Circuit has “consistently recognized the
10 difficulties in proving certainty in the medical sciences.”)

11 The assertions by Drs. Morris and Grassi in their depositions that they formed their
12 opinions on core issues in this case using a “medical certainty” standard are thus “wholly
13 inconsistent with *Daubert* and the fundamental premise of Rule 702.” *McClellan v.*
14 *I-Flow Corp.*, 710 F. Supp. 2d 1092, 1101 (D. Or. 2010).

15 2. The Criminal Law “Beyond a Reasonable Doubt” Standard
16 Employed by Defendants’ Experts Lacks Relevance.

17 Dr. Morris’s and Dr. Grassi’s opinions should be excluded because they fail
18 *Daubert*’s relevance test. Under *Daubert*, The court is tasked with conducting a
19 preliminary assessment to “ensure that any and all scientific testimony or evidence
20 admitted is not only relevant, but reliable.” *Daubert, supra*, at 509 U.S. at 589. As
21 detailed below, opinions based on these criminal law standards are not relevant in a civil
22 case.

23 In the real world of clinical medicine, physicians do not have the luxury of waiting
24 until a cause-and-effect relationship is definitively established before diagnosing and
25 treating their patients. If it were otherwise, patients would die, scientific research would
26 languish, and the state of medical knowledge would never advance. As the U.S. Supreme
27 Court has recognized, outside the courtroom, it is a fallacy that scientists insist on
28 certainty or near certainty in making judgments. “[M]edical professionals and researchers

1 do not limit the data they consider to the results of randomized clinical trials or to
 2 statistically significant evidence.” *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 40-
 3 42 (2011).

4 Likewise, if courts were to impose such a stratospheric standard for admissibility
 5 on medical expert testimony, *no* plaintiff could prove causation at trial. *McClellan*, 710
 6 F. Supp. 2d at 1101. Although Dr. Morris purports to use the beyond-a-reasonable-doubt
 7 methodology in his own practice, Exhibit 2 (Morris Dep.) at 139-140, it is not the norm in
 8 clinical medicine as practiced by most physicians or researchers, nor is it an accepted
 9 standard in the courtroom. In short, the absolute certainty standard espoused by
 10 Drs. Morris and Grassi is factually and legally irrelevant in a civil case. These experts
 11 should not be permitted to express their opinions based on this standard.

12 3. The Criminal Law Standard for Causation Adopted by Defendants’
 13 Experts Is Not Helpful to the Jury.

14 Nor will such testimony “assist the trier of fact.” To the contrary, it will tend to
 15 obfuscate and confuse. Opinions that are based on the incorrect legal standard cannot be
 16 helpful to the jury and, in fact, create confusion. The very purpose of expert testimony is
 17 to help the jury understand the evidence or determine a fact in issue. Fed. Rule Evid. 702
 18 (a). “To fulfill its gate-keeping role, the court must strike ‘the appropriate balance
 19 between admitting reliable, helpful expert testimony and excluding misleading or
 20 confusing testimony.’” *United States v. Rincon*, 28 F.3d 921, 926 (9th Cir.1994). “The
 21 dispositive question is whether the testimony will ‘assist the trier of fact to understand the
 22 evidence or to determine a fact in issue...’” *Ambrosini v. Labarraque*, 101 F.3d 129, 135
 23 (D.C.Cir.1996)

24 The defendants’ experts’ insistence on being “certain beyond any reasonable
 25 doubt” or “more than 90% certain” has the prejudicial effect of holding plaintiffs and their
 26 experts to an erroneously high burden of proof. Witness testimony couched in the phrase
 27 “beyond a reasonable doubt” is powerful and resonant. And when uttered from the
 28 mouths of experts, this testimony poses a strong risk of misleading the jury to give it

1 undue weight. *See Elsayed Mikhtar*, 299 F.3d at 1063-64 (cautioning that “the aura of
2 authority experts exude” can lead juries to give their opinions more weight).

3 One key issue in all of these Bard IVC filter cases is whether the Bard retrievable
4 filters have an unacceptably high fracture rate and overall complication rate (fracture,
5 migration, perforation, and tilt). Plaintiffs’ experts opine that Bard’s retrievable filters
6 have elevated and unacceptably high fracture rates, and they base their opinions on
7 multiple lines of evidence, including peer-reviewed, published studies, internal Bard
8 assessments, adverse event reporting disparities, bench tests, and expert engineering
9 assessments.

10 By contrast, Drs. Grassi’s and Morris’s reliance on the “more than 90% certainty”
11 or “certain beyond any reasonable doubt” is an improper method of assessing the
12 adequacy of evidence. As quoted above, Dr. Morris testified about “the literature that’s
13 available regarding IVC filters,” stating, “How can I make 100 percent certain opinions
14 based on literature which is less than Level I or Level II evidence?” Morris Dep., 141:24-
15 142: 14. *See also* Morris Rept. at 24-25, Exhibit 1 [4/13/17] (discussing the levels of
16 evidence, and asserting that the IVC studies are not Level I or Level II evidence).

17 Expert testimony that medical propositions can be proved only with evidence from
18 Level I and Level II evidence (*i.e.*, multiple randomized clinical trials) will confuse and
19 mislead the jury to believe that plaintiffs’ legal burden of proof is beyond a reasonable
20 doubt, not more likely than not. *Matrixx*, 563 U.S. 27 at 40-42. Moreover, the “beyond a
21 reasonable doubt” testimony contradicts the jury instruction that Plaintiffs must prove
22 their claims by a preponderance of the evidence.

23 Finally, differing opinions based on the heightened “beyond a reasonable
24 doubt” standard are impossible for the jury to reconcile with opinions based on the “more
25 likely than not,” standard. The risk that this will lead to an incorrect verdict is foreseeable
26 and not theoretical. *See Smith v. Schriro*, 813 F.3d 1175, 1199 (9th Cir. 2016) (“If a
27 trained psychiatrist has difficulty with the categorical ‘beyond a reasonable
28 doubt’ standard, the untrained lay juror—or indeed even a trained judge—who is required

1 to rely upon expert opinion could be forced by the criminal law standard of proof to reject
 2 commitment for many patients desperately in need of institutionalized psychiatric care.”).
 3 Expert opinion based on an incorrect legal standard should therefore be excluded.

4 **B. Dr. Grassi’s and Dr. Morris’s opinions based on speculation and**
 5 **anecdotal personal experience should be excluded as unreliable.**

6 The opinions of Dr. Morris and Dr. Grassi that are based on speculation and
 7 anecdotal personal experience should also be excluded because they are unreliable and
 8 prejudicial. The Ninth Circuit has excluded opinion testimony based on personal
 9 experience: “As the district court found, [the experts’] conclusions were based on their
 10 ‘personal opinions and speculation rather than on a systematic assessment of
 11 [Defendant’s] athletic facilities and programs.’ But personal opinion testimony is
 12 inadmissible as a matter of law under Rule 702 . . . and speculative testimony is inherently
 13 unreliable.” *Ollier v. Sweetwater Union High Sch. Dist.*, 768 F.3d 843, 861 (9th Cir.
 14 2014) (citations omitted); *see also Berk v. St. Vincent’s Hosp. & Med. Ctr.*, 380 F. Supp.
 15 2d 334, 354 (S.D.N.Y. 2005) (“An anecdotal account of one expert’s experience, however
 16 extensive or impressive the numbers it encompasses, does not by itself equate to a
 17 methodology, let alone one generally accepted by the relevant professional community.”);
 18 *Smith v. Pfizer Inc.*, No. 3:05-0444, 2010 U.S. Dist. LEXIS 47698, at *7-8 (M.D. Tenn.
 19 May 14, 2010) (“The court agrees with the plaintiff that, compared to [analysis of clinical
 20 studies and medical literature], the fact that ‘[n]o patient has ever reported suicidality to
 21 [the expert] in connection with his or her Neurontin use,’ . . . is much less probative of
 22 Neurontin’s tendency to increase the risk of suicide. It would be improper for the jury to
 23 rely on this evidence to assess general causation, because the number of [the expert]’s
 24 patients is, relatively speaking, insignificant. Because this kind of anecdotal evidence
 25 might unduly prejudice the jury, the court will exclude this comment.”).

26 In his deposition, Dr. Morris admitted that opinion that “most limb fractures remain
 27 asymptomatic,” was “speculation”; it should be excluded. (*Compare* Morris report, p. 25,
 28 with Morris deposition p. 212:24-213:6).

Similarly, Dr. Grassi's opinion that he did not see "unexpectedly high complication rates with Bard filter devices," is merely anecdotal and not based on sufficient data. Dr. Grassi never systematically reviewed his patients or determined the status the Bard filters generally. His opinion as to the Recovery filters is particularly misleading because he did not implant or retrieve any of them. As to the later devices, he retrieved approximately six of each (G2/G2x, Eclipse, Meridian, and Denali). Exhibit 2, Morris Dep. at 51-63. Even then, approximately one-fourth of the G2 retrievals resulted in a perforation. *Id.* at 56.² As in *Pfizer*, 2010 U.S. Dist. LEXIS 47698, at *7-8, the numbers available to Dr. Grassi are "relatively speaking, insignificant," and allowing Dr. Grassi's opinions on this point would unduly prejudice the jury.

IV. CONCLUSION

Drs. Morris and Grassi base their causation opinions on an erroneous methodology when they form their opinions using a "beyond a reasonable doubt" standard. Their testimony is irrelevant, not helpful, and highly prejudicial. Further, the speculative opinions and those based on anecdotal personal experience are unreliable. Accordingly, the Court should bar the experts from expressing these opinions.

RESPECTFULLY SUBMITTED this 24th day of August, 2017.

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² This opinion should be excluded for the additional reason that the "expected" rate of complications is not defined.

CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of August, 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti